



Questions and Answers about Guillain-Barré Syndrome among Recipients of Menactra® Meningococcal Conjugate Vaccine 10/19/2006

Does Menactra Meningococcal Conjugate Vaccine cause Guillain-Barré Syndrome?

No, at this time we can not say that Menactra vaccine causes Guillain-Barré Syndrome.

Why are you making this announcement at this time?

We are updating the public with new information about a possible but unproven rare risk that Guillain-Barré Syndrome (GBS) could be associated with Menactra® Meningococcal Conjugate Vaccine. This information was first identified and shared with the public in October 2005. We also want to make people aware of this matter so that they will report possible cases of Guillain-Barré Syndrome to the Vaccine Adverse Event Reporting System (VAERS) that have not been previously submitted.

How can I report a case of Guillain-Barré Syndrome after Menactra vaccine or any vaccine?

Because of the potentially serious nature of this matter, CDC and FDA are asking any persons with knowledge of any possible cases of GBS occurring after Menactra to report them to the Vaccine Adverse Event Reporting System (VAERS) to help the agencies further evaluate the matter. Individuals can report to VAERS on the web at www.vaers.hhs.gov or by phone at 1-800-822-7967.

What are the risks from meningococcal vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of meningococcal vaccine causing serious harm, or death, is extremely small.

Mild problems -Up to about half of people who get meningococcal vaccines have mild side effects, such as redness or pain where the shot was given. If these problems occur, they usually last for 1 or 2 days. A small percentage of people who receive the vaccine develop a fever.

Severe problems-Serious allergic reactions, within a few minutes to a few hours of the shot, are very rare. A few cases of Guillain-Barré Syndrome, a serious nervous system disorder, have been reported among people who received Menactra vaccine. There is not enough evidence yet to tell whether any of these cases were caused by the vaccine. This is being investigated by health officials. All persons who have become ill with Guillain-Barré Syndrome following Menactra immunization have recovered or are recovering.

Why are you continuing to recommend this vaccine?

Meningococcal infection, which Menactra prevents, is a major cause of invasive meningococcal disease, affecting approximately 1 in 100,000 people annually. The infection can be life threatening: 10-14 percent of cases are fatal and 11-19 percent of survivors may have permanent disability. As we learn more information, the benefits and risks of the vaccine will be reassessed.

What is Guillain-Barré Syndrome?

Guillain Barré Syndrome (GBS) is a serious rare neurological disorder that can occur, often in healthy individuals, either spontaneously or after certain infections. GBS typically causes increasing weakness in the legs and arms that can be severe and require hospitalization. Persons who become ill with GBS usually make a full recovery.

What causes Guillain-Barré Syndrome?

Many things can cause Guillain-Barré Syndrome (GBS), including common infections, such as sore throats and other infections that occur in the community.

What are FDA and CDC doing to investigate?

FDA and CDC continue to monitor reports to the Vaccine Adverse Event Reporting System (VAERS), and encourage reporting of any cases of GBS after Menactra to VAERS. CDC's Vaccine Safety Datalink and other databases are being queried to identify any cases of GBS after Menactra. Other types of studies to further evaluate the risk are being planned. Because GBS is very rare, scientific study of this issue is challenging and requires extremely large databases. The CDC is also communicating with and obtaining input into the investigation from the Advisory Committee on Immunization Practices, the American Academy of Pediatrics and the National Vaccine Advisory Committee about this investigation.

Will any further action be taken?

Yes, CDC and FDA will continue to closely monitor the situation. There is not a simple number of cases that would have to be reported before CDC or FDA take additional action. The reason is that GBS can occur in the absence of vaccination, and thus every case needs to be evaluated carefully for possible causes. The timing of GBS following vaccination, clinical factors, and the total number of people vaccinated are important to consider as well. CDC's Advisory Committee on Immunization Practices and other advisory groups will also be considering this updated information.

Are you communicating with the company who makes this vaccine?

Yes, FDA and CDC are working closely with the vaccine manufacturer, sanofi pasteur, Inc., and will continue to do so as we actively investigate the situation.

Is there another vaccine to protect against this disease?

Yes, there is another Meningococcal vaccine that is licensed by FDA called Menomune. Menomune has different characteristics and it is not recommended for routine use in civilians but only for certain individuals at high risk. Additionally it is in limited supply.

Doesn't flu vaccine cause GBS?

No, only in 1976 was flu vaccine associated with a rare risk of GBS. The Institute of Medicine (IOM) Immunization Safety Review Committee recently concluded that the evidence favors acceptance of a causal relationship between 1976 swine influenza vaccine and GBS, but the evidence is inadequate to accept or reject a causal relationship between GBS and influenza vaccines administered since then. For more information about this report see IOM report on Influenza Vaccines and Neurological Complications <http://www.nap.edu/books/0309090865/html> FDA and CDC continually monitor the safety of influenza vaccine.

Where can I get more information about Meningococcal vaccine?

You can get more information about Meningococcal vaccine through the CDC Vaccine information statement <http://www.cdc.gov/nip/publications/VIS/vis-mening.rtf> . The CDC Meningococcal Disease and Meningococcal Vaccines fact sheet http://www.cdc.gov/nip/vaccine/mening/mening_fs.htm The CDC advisory Committee on Immunization Practices Recommendations for Prevention and Control of Meningococcal Disease <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5407a1.htm>

Where can I get more information about GBS following Menactra Vaccine?

For more information about GBS following Menactra® vaccine see <http://www.cdc.gov/od/science/iso/gbsfactsheet.htm>